UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,531	01/11/2002	Jeanne Maruani	IVD978-2	4927

27546 7590 03/10/2004

SANOFI-SYNTHELABO INC.
9 GREAT VALLEY PARKWAY
P.O. BOX 3026
MALVERN, PA 19355

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,531	MARUANI ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-29 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-29 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on December 3, 2003 have been received and entered into the application.

Action Summary

Claims 19-23, 26-29 and 39 of record rejected under 35 U.S.C. 103 (a) over Barth et al. (U.S.Patent No. 5624941) of record and Baroni et al. (U.S.Patent No. 5488151) of record is maintained for the reasons stated in the previous office action.

Claims 19-22, 24 and 25 of record rejected under 35 U.S.C. 103 (a) over Barth et al. (U.S.Patent No. 5624941) of record and Brazzell et al. (U.S.Patent No. 5578638) of record is maintained for the reasons stated in the previous office action.

Claims 19-22 and 25 of record rejected under 35 U.S.C. 103 (a) over Barth et al. (U.S.Patent No. 5624941) of record and Cecchi et al. (U.S.Patent No. 5624941) of record is maintained for the reasons stated in the previous office action.

Response to Arguments

Applicant's arguments filed on December 3, 2003 have been fully considered but they are not persuasive.

Applicants argue that Claims 19-23, 26-29 and 39 of record rejected under 35 U.S.C. 103 (a) over Barth et al. (U.S.Patent No. 5624941) of record and Baroni et al.

(U.S.Patent No. 5488151) of record is believed to be overcome in view of the amendments to the claims which are now direct to pharmaceutical composition for the treatment of appetency disorder which are neither taught nor suggested by the disclosure of Barth et al. or Baroni et al. when taken alone or in combination. This is not persuasive because Applicants' recitation in amended claim 19 of an intended use for the treatment of appetency disorders not found in the prior art does not represent a patentable limitation in a composition claim since such fails to impart any physical limitation to the active agents in the composition as modified by the cited references. One would have been motivated to conveniently combine each of the active agents (CB1 receptor antagonist and B3 agonist) in a composition to treat glaucoma. In this case it would have been prima facie obvious to combine CB1 receptor antagonist and B3 agonist in a composition cojointly to treat glaucoma. It is noted that the resulted composition by combining the prior art would result in an identical composition as claimed as claimed by the Applicants and therefore it would be capable of performing the intended use. It is noted that Applicants are claiming composition not a method of use claims.

Applicants next argue Claims 19-22, 24 and 25 of record rejected under 35 U.S.C. 103 (a) over Barth et al. (U.S.Patent No. 5624941) of record and Brazzell et al. (U.S.Patent No. 5578638) of record is believed to be overcome in view of the amendments to the claims which are now direct to pharmaceutical composition for the treatment of appetency disorder which are neither taught nor suggested by the disclosure of Barth et al. or Brazzell et al. when taken alone or in combination. Again,

this is not persuasive because Applicants' recitation in amended claim 19 of an intended use for the treatment of appetency disorders not found in the prior art does not represent a patentable limitation in a composition claim since such fails to impart any physical limitation to the active agents in the composition as modified by the cited references. One would have been motivated to conveniently combine each of the active agents (CB1 receptor antagonist and B3 agonist) in a composition to treat glaucoma. In this case it would have been prima facie obvious to combine CB1 receptor antagonist and B3 agonist in a composition cojointly to treat glaucoma. It is noted that the resulted composition by combining the prior art would result in an identical composition as claimed as claimed by the Applicants and therefore it would be capable of performing the intended use. Again, it is noted that Applicants are claiming composition not a method of use claims.

Applicants lastly argue Claims 19-22 and 25 of record rejected under 35 U.S.C. 103 (a) over Barth et al. (U.S.Patent No. 5624941) of record and Cecchi et al. (U.S.Patent No. 5624941) of record is maintained for the reasons stated in the previous office action. This is not persuasive because Applicants' recitation in amended claim 19 of an intended use for the treatment of appetency disorders not found in the prior art does not represent a patentable limitation in a composition claim since such fails to impart any physical limitation to the active agents in the composition as modified by the cited references. One would have been motivated to conveniently combine each of the active agents (CB1 receptor antagonist and B3 agonist) in a composition to treat glaucoma. In this case it would have been prima facie obvious to combine CB1

receptor antagonist and B3 agonist in a composition cojointly to treat glaucoma. It is noted that the resulted composition by combining the prior art would result in an identical composition as claimed as claimed by the Applicants and therefore it would be capable of performing the intended use. It is noted that Applicants are claiming composition not a method of use claims.

In view of the above Office Action of June 13, 2003 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

Claims 19-23, 26-29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (U.S.Patent No. 5624941) and Baroni et al. (U.S.Patent No. 5488151).

Barth et al. teach Applicants active agent, CB_1 receptor antagonist set forth in claims 19,21 and 39 useful for the treatment of glaucoma. (abstract, column 2, column 88, claim 27). Barth et al. also teach the dosage range of the CB_1 receptor antagonist within the Applicants' range set forth in claims 27-29. (column 27, lines 10-35).

Baroni et al. teach Applicants active agent, B_3 agonist set forth in claims 19, 23 and 26 useful for the treatment of glaucoma. (abstract, columns 1 and 2, column 2, lines 32-35, column 4, claim 1). Baroni et al. also teach the dosage range of the B_3 agonist within the Applicants' range set forth in claims 27-29. (column 3, line 63 – column 4, line 11).

The claims differ from the cited references in claiming combination of CB1 receptor antagonist, and B_3 agonist, to treat glaucoma. To employ combinations of CB1 receptor antagonist and B_3 agonist to treat glaucoma would have been obvious because all the components are well known individually for treating glaucoma. It would be expected that the combination of components would treat glaucoma as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Therefore, it would have been prima facie obvious to combine CB_1 receptor antagonist, and B_3 agonist composition cojointly in a formulation to treat glaucoma. It is noted the intended use set forth in claim 19 does not have a patentable weight in the composition claims.

Claims 19-22, 24 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (U.S.Patent No. 5624941) and Brazzell et al. (U.S.Patent No. 5578638).

Barth et al. teach Applicants active agent, CB_1 receptor antagonist set forth in claims 19 and 21 useful for the treatment of glaucoma. (abstract, column 2, column 88, claim 27).

Brazzell et al. teach B_3 agonist (formula IV) useful for the treatment of glaucoma. (abstract, column 1. lines 7-15, columns 3-7).

The claims differ from the cited references in claiming combination of CB_1 receptor antagonist, and B_3 agonist, to treat glaucoma. To employ combinations of CB1 receptor antagonist and B_3 agonist to treat glaucoma would have been obvious

because all the components are well known individually for treating glaucoma. It would be expected that the combination of components would treat glaucoma as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Therefore, it would have been prima facie obvious to combine CB_1 receptor antagonist, and B_3 agonist composition cojointly in a formulation to treat glaucoma.

It is noted the intended use set forth in claim 19 does not have a patentable weight in the composition claims.

Claims 19-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (U.S.Patent No. 5624941) and Cecchi et al. (U.S.Patent No. 5130339).

Barth et al. teach Applicants active agent, CB_1 receptor antagonist set forth in claims 19 and 21 useful for the treatment of glaucoma. (abstract, column 2, column 88, claim 27).

Cecchi et al. teach B_3 agonist (formula V) useful for the treatment of glaucoma. (Abstract, column 1, line 38 – column 2, line 21, column 17, lines 4-12).

The claims differ from the cited references in claiming combination of CB1 receptor antagonist, and B_3 agonist, to treat glaucoma. To employ combinations of CB1 receptor antagonist and B_3 agonist to treat glaucoma would have been obvious because all the components are well known individually for treating glaucoma. It would be expected that the combination of components would treat glaucoma as well. The motivation for combining the components flows from their individually known common

utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Therefore, it would have been prima facie obvious to combine CB_1 receptor antagonist, and B_3 agonist composition cojointly in a formulation to treat glaucoma. It is noted the intended use set forth in claim 19 does not have a patentable weight in the composition claims.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
February 25, 2004